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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/511,882

10/19/2004

Bodo Kuklinski

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EXAMINER

SCHUBERG, LAURA J

ART UNIT

PAPER NUMBER

1657

MAIL DATE

DELIVERY MODE

09/23/2009

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/511,882	Applicant(s) KUKLINSKI ET AL.	
	Examiner Laura Schuberg	Art Unit 1657	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 19 June 2009.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 9, 10 and 14-22 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 9, 10 and 14-22 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

This action is responsive to papers filed 06/19/2009. No claims have been amended, newly added or newly canceled.

Claims 9, 10, 14-22 are pending and have been examined on the merits.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation

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under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 9, 10, and 14-22 remain rejected under 35 U.S.C. 103(a) as being unpatentable over Fuchs et al (WO 01/97634 A1) in view of Institut Regionalnykh Problem Pitaniya (SU 1740002 A1-from IDS, relevance explained in Russian Search Report) or Bühlbäcker (Verlag, 1996, relevance explained in Applicant's disclosure, page 8).

Claim 9 is drawn to a method of treating neurodermatitis or psoriasis in a subject comprising: obtaining a composition comprising a mare milk concentrate dried on a biologically inert, disperse matrix, and orally administering the composition to a subject, wherein neurodermatitis or psoriasis is treated in the subject.

Claim 10 is drawn to the method of claim 9, wherein the subject is a human.

Claim 14 is drawn to the method of claim 9, wherein the matrix is a highly disperse silicon dioxide.

Claim 15 is drawn to the method of claim 9, wherein the mare milk concentrate was dried at a temperature of from 10 to 50OC.

Claim 16 is drawn to the method of claim 15, wherein the mare milk concentrate was dried at a temperature of from 35 to 40OC.

Claim 17 is drawn to the method of claim 9, wherein the mare milk concentrate was dried at a pressure of from 1 to 50 mbar.

Claim 18 is drawn to the method of claim 17, wherein the mare milk concentrate was dried at a pressure of from 10 to 30 mbar.

Claim 19 is drawn to the method of claim 9, further comprising drying the mare milk concentrate on the matrix.

Claim 20 is drawn to the method of claim 9, wherein the composition further comprises at least one essential fatty acid.

Claim 21 is drawn to the method of claim 20, wherein the essential fatty acid is a vegetable essential fatty acid.

Claim 22 is drawn to the method of claim 9, wherein the composition further comprises at least one of hydrogen carbonate, potassium, carbonate, citrate, calcium, magnesium, vitamin C, vitamin E, niacin, zinc, iron, beta-carotene, pantothenic acid, manganese, vitamin B6, vitamin B2, vitamin B1, copper, sodium, biotin, folic acid, molybdenum, selenium, xanthan, fructose, citric acid, or vitamin B 12. (Applicant has elected vitamin B1.)

Fuchs teaches an oral composition comprising highly unsaturated fatty acids on a biologically inert matrix (p.9) and drying the composition at a pressure of 10-30 mbar and a temperature of 30-36 ° C (p.12). The reference also teaches that it is advantageous to add mare's milk before drying (p.15). It is also taught that it is especially advantageous if the composition is applied on a highly dispersed silicon dioxide matrix (p.12). The composition taught by the reference also contains linolenic

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acid (p.20), which is a vegetable essential fatty acid. Vitamin B1 is present in mare's milk and therefore inherently present in the composition. Fuchs teaches that highly unsaturated fatty acids are of a high biological and nutrition-medical relevance, especially for skin metabolism, neurodermatitis and psoriasis (p.3) and that the composition taught contains at least one unsaturated fatty acid. The disclosure of the skin disorders, neurodermatitis and psoriasis, and their connection with the need for the highly unsaturated fatty acids would indicate that administration of the referenced composition, which contains highly unsaturated fatty acids, would be necessary. In addition, the reference does teach where the subject is human and that the dry concentrates of mare's milk have beneficial effects on humans (p.15).

Russian patent (SU 1740002 A1) teaches the use of specially prepared mare milk (kumiss) for oral intake for the treatment of neurodermatitis and eczema (as described in Russian Search Report-English Translation page 2).

Alexander Bühlbäcker describes the use of native mare milk as a food additive in the treatment of neurodermatitis (as described in the Spec page 8).

Therefore, it would have been obvious to one of ordinary skill in the art to use the composition of Fuchs that contains mare's milk for the treatment and prevention of dry skin diseases such as neurodermatitis and psoriasis since the highly unsaturated fatty acids in the composition are taught by Fuchs to be important for skin metabolism and these skin disorders (p.3) and mare's milk contains highly unsaturated fatty acids. One of ordinary skill in the art would have also been motivated by the Russian patent and Bühlbäcker to use the composition of Fuch's for these skin diseases because mare's

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milk (found in an embodiment of Fuchs's composition) is known to be used for the treatment of neurodermatitis and like skin diseases. One of ordinary skill in the art would have had a reasonable expectation of success since Fuchs provides a composition that ensures a fine surface distribution of the oil particles so that sufficient quantities of unsaturated fatty acids are included (p.7) and teaches embodiments including mare's milk. One of ordinary skill in the art would have also had a reasonable expectation of success since Fuchs does NOT teach that the embodiment of the method including mare's milk is not intended for the treatment of neurodermatitis or psoriasis, nor does Fuchs indicate that the embodiment including mare's milk is limited to only certain disorders.

Therefore, the combined teachings of Fuchs and the Russian patent (SU 1740002 A1) or Bühlbäcker render obvious Applicant's invention as claimed.

Response to Arguments

Applicant's arguments filed 06/19/2009 have been fully considered but they are not persuasive.

Applicant argues that the currently claimed method of treating neurodermatitis or psoriasis is non-obvious over the cited references because the results of the claimed method were unexpected. Applicant asserts that the Bühlbäcker reference required a minimum treatment time of 10 months and was ineffective if given alone. Applicant asserts that the claimed method unexpectedly gives results in one month. Applicant

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asserts that since mare's milk does not contain alcohol (as koumiss-fermented mare's milk- does), one could not have predicted a similar benefit of mare's milk based on the properties of koumiss cited in the SU 1740002 reference (translation page 4). Applicant asserts that the unexpected results of the claimed method could not have been predicted by the Fuchs reference or the SU 1740002 because there is no data regarding treatments with either native mare's milk or a dried mare's milk concentrate and because Fuchs does not specifically disclose or suggest using the reference composition as a treatment for neurodermatitis or psoriasis.

This is not found persuasive because of several reasons. First, the obviousness rejection relies upon the teaching of Bühlbäcker and SU 1740002 to add additional motivation to the teaching of Fuchs that applying the composition of Fuchs to the treatment of neurodermatitis and psoriasis would be obviously beneficial. One of ordinary skill in the art would expect the composition of Fuchs to perform better than the composition of Bühlbäcker because Fuchs teaches that the reference method is significantly improved over the prior art. Fuchs teaches that the reference method produces a composition in which many of the prior known disadvantages are circumvented and in which the high health promoting value of the unsaturated fatty acids can be maintained (page 7). These unsaturated fatty acids are what Fuchs maintains are very important for skin metabolism –specifically neurodermatitis and psoriasis (page 3). Clearly Fuchs intended for this improved composition (that was suggested to also include mare's milk on a biologically inert, disperse matrix) to be used in the treatment of neurodermatitis and psoriasis. Clearly, one of ordinary skill in the art

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would have expected the composition of Fuchs to perform better than the Bühlbäcker composition because of the improved formulation and the inclusion of additional health promoting ingredients.

Second, while the SU 1740002 reference attributes some of the secondary properties of koumiss to its alcohol content, the primary skin benefits are owed to the fact that koumiss has a full value amino acid formulation and the koumiss albumins are represented by a readily available albumin fraction which remedies the albumin loss that occurs in connection with a cutaneous and inflammatory process (festering, desquamation) (page 4). Clearly, the albumins (proteins) in the mare's milk, not the alcohol from the fermentation, are suggested as responsible for the effectiveness of koumiss in the treatment of the primary skin symptoms of neurodermatitis or psoriasis. In addition, not only would SU 1740002 motivate one of ordinary skill in the art to apply the Fuch's composition containing mare's milk to the treatment of skin diseases such as neurodermatitis or psoriasis, there would have been a reasonable expectation of attaining results in about a month because SU 1740002 teaches that fermented mare's milk orally administered to patients gives results in less than one month (page 3) and Fuch's teaches that the mare's milk dried on a biologically, inert, disperse matrix provides increased stability and high health promoting values as well as containing the unsaturated fatty acids important for treating neurodermatitis or psoriasis. Clearly treatment results in one month are not unexpected for an improved, stable composition of mare's milk.

In conclusion, the teaching of the Fuchs reference provides the same composition as claimed by Applicant and teaches that this composition (the composition disclosed in the reference) is important for skin metabolism and suggests that it be administered as a skin treatment for neurodermatitis or psoriasis (see page 3 of translation). The teachings of SU 1740002 and Bühlbäcker provide additional motivation and reasonable expectation of success in using a composition containing mare's milk in the treatment of neurodermatitis or psoriasis. In addition, the achievement of results in about a month are not deemed to be unexpected in view that the Fuch's composition is taught to be improved over prior compositions and the SU 1740002 reference teaches that results in less than a month are attained by using fermented mare's milk (which contains the same albumins as mare's milk which are primarily responsible for the improved skin results).

Applicant argues that a review of the translation of the Fuch's reference indicates that word "improve" or "improved" was used only once, and that this was in regard to improved shelf life of the product. Applicant asserts that this is not a sufficient motivation for the establishment of obviousness.

This is not found persuasive because a closer review of the translation reveals that other terms are used to convey to the reader that the Fuch's reference disclosed a composition that was improved over the compositions of the prior art. For example, the Fuch's reference states that "it is the object of the invention to make available a process for producing a concentrate from unsaturated fatty acids, in which the above mentioned disadvantages are circumvented, and in which however the high health promoting value

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of the unsaturated fatty acids can be maintained” (page 7 of the translation). Also the use of the phrase “a further advantage” (page 10 of the translation) with regard to the qualities of the reference composition implies that the composition was an improvement over the prior art compositions as well. The addition of mare’s milk was also specified as an advantage as well (page 15 of the translation).

Applicant argues that much of the Examiner's arguments are based on presumed intentions, not facts. Applicant asserts that the Examiner makes conclusionary assertions that Fuchs “clearly intended” to include mare’s milk in the formulation and use that formulation in the treatment of neurodermatitis and psoriasis. Applicant argues that factual findings made by the Examiner are the necessary underpinnings to establish obviousness. Applicant asserts that the Examiner’s presumptions of the intentions of the Fuchs reference have not been supported by factual findings.

This is not found persuasive because the Fuchs reference explicitly states the advantages of the composition (page 10 of the translation) as well as the advantages of including milk such as mare's milk in the composition (page 15 of the translation) and the importance of using an unsaturated fatty acid composition (such as the reference composition) for the treatment of neurodermatitis and psoriasis (page 3 of the translation) and the suggestion to formulate the composition in different medicament forms (page 23 of the translation). These express statements made in the Fuchs reference provide factual evidence that support the conclusion that the composition of the Fuchs reference was intended to be used in the treatment of different skin disorders, specifically neurodermatitis and psoriasis.

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Applicant argues that there are no identified facts that support the Examiner's conclusion that a person of ordinary skill in the art would have expected that the mare's milk concentrate dried on a biologically inert, disperse matrix would be more effective at treating neurodermatitis or psoriasis than the native mare's milk disclosed in Bühlbäcker.

This is not found persuasive because one of ordinary skill in the art would expect the composition of Fuchs to perform better than the composition of Bühlbäcker because Fuchs teaches that the reference method is significantly improved over the prior art. Fuchs teaches that the reference method produces a composition in which many of the prior known disadvantages are circumvented and in which the high health promoting value of the unsaturated fatty acids can be maintained (page 7). These unsaturated fatty acids are what Fuchs maintains are very important for skin metabolism – specifically neurodermatitis and psoriasis (page 3). Clearly Fuchs intended for this improved composition (that was suggested to also include mare's milk on a biologically inert, disperse matrix) to be used in the treatment of neurodermatitis and psoriasis. Clearly, one of ordinary skill in the art would have expected the composition of Fuchs to perform better than the Bühlbäcker composition because of the improved formulation and the inclusion of additional health promoting ingredients (the additional unsaturated fatty acids).

Applicant argues that to improve the efficacy of mare's milk in treating neurodermatitis and psoriasis, the teachings of Bühlbäcker and SU 1740002 would suggest to a person of ordinary skill in the art that one would need to ferment the mare's

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milk. Applicant asserts that the drying process of the Fuchs reference would be incompatible with the teachings of SU 1740002 regarding the sedative effect of the alcohol in the koumiss. Applicant asserts that the proposed modification or combination of the prior art would change the principle of the operation of the prior art invention being modified or render it unsatisfactory for its intended purpose and thus the teachings of the references are not sufficient to render the claims *prima facie* obvious.

This is not found persuasive for several reasons. First of all, the teachings of Bühlbäcker and SU 1740002 are relied on in the obviousness rejection to provide motivation for one of ordinary skill in the art to select those embodiments in the Fuchs reference that contain mare's milk for the treatment of skin disorders such as neurodermatitis and psoriasis. The fact that mare's milk had been previously used to treat these specific disorders with some measure of success provides a motivation to select mare's milk over the other types of milk listed as acceptable in the Fuchs reference composition as well.

Second, while the SU 1740002 reference attributes some of the secondary properties of koumiss to its alcohol content, the primary skin benefits are owed to the fact that koumiss has a full value amino acid formulation and the koumiss albumins are represented by a readily available albumin fraction which remedies the albumin loss that occurs in connection with a cutaneous and inflammatory process (festering, desquamation) (page 4). Clearly, the albumins (proteins) in the mare's milk, not the alcohol from the fermentation, are suggested as responsible for the effectiveness of koumiss in the treatment of the primary skin symptoms of neurodermatitis or psoriasis.

Third, any loss of a sedating effect caused by the drying of the mare's milk in the composition of the Fuchs reference could easily be compensated by the addition of other sleep promoting agents (such as antihistamines) if needed. Fuchs specifically suggests that the addition of other medicaments to the composition is acceptable as well (page 16 of the translation). Therefore the combination of references does not change the operation of the Fuchs reference composition nor render it unsatisfactory for its intended purpose.

Therefore the claims remain rejected under the prior art as described in the rejection above.

Conclusion

No claims are allowed.

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of

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the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Laura Schuberg whose telephone number is (571)272-3347. The examiner can normally be reached on Mon-Fri 8:00-4:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jon Weber can be reached on (571) 272-0925. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Laura Schuberg

/JON P WEBER/

Supervisory Patent Examiner, Art Unit 1657